

**REMARKS**

This paper is responsive to the Office Action dated February 12, 2009. Claims 1-21 were the subject of the present examination. Claims 22-28 were withdrawn from consideration based upon a restriction requirement.

**Objections to Specification:**

The abstract of the disclosure was objected to because claimed subject matter was not present within the specification (MPEP 608.01(b)). The specification has been amended, and an amended abstract of the disclosure is presented herein.

The disclosure was objected to because certain ranges listed in claims 3, 4 and 7 were not specifically recited in the specification. Claims 3 and 7 have been canceled. The relevant limitation of claim 3 has been added to claim 1. The specification has been amended as set forth above to include the limitations that had previously been set forth in said claim 3, and to set forth the limitations of claim 4.

**Sec. 103(a) rejections:****Claims 1-6, 10, 14-15, and 20-21.**

Claims 1-6, 10, 14-15, and 20-21 were rejected under 35 USC 103(a) as being unpatentable over Parker (US 5,700,253) in view of Lepulu et al (US 6,533,770).

Claim 1, as amended herein, is directed to an introducer sheath comprising an inner tube having a passageway extending longitudinally therethrough, the passageway having a substantially uniform inner diameter of from 16 to 30 French. A coil has a plurality of coil turns extending longitudinally around the inner tube, and a plurality of predetermined spacings between the coil turns. An outer tube positioned longitudinally around the coil and the inner tube

is connected to the inner tube through the spacings between said turns. The outer tube has a durometer of about 30 to 60 on the Shore D hardness scale.

As noted, this claim has been amended to narrow the inner diameter of the inner tube to 16 to 30 French. In addition, the claim has been amended to specify that the outer tube has a durometer from about 30 to 60 on the Shore D hardness scale. These limitations were previously in claims 3 and 8, respectively. Claims 3 and 7 have been cancelled, and claim 8 has been amended remove the limitation added to claim 1. In addition, claim 4 has been amended to change its dependency to claim 1. New dependent claim 29 has been added. Claim 29 specifies that the marker tube and the outer tube are formed from the same polymer having the same durometer, and that these tubes are bonded together. This limitation is supported by paragraph [0026] of the specification.

The sheaths claimed herein, having inner diameters in the range of 16 to 30, are typically considered in the art as large diameter sheaths. As stated in the present specification (paragraph [0023]), it is an important consideration of such sheaths that the material of the outer tube be sufficiently flexible so that the large diameter sheath can navigate the tortuous pathways encountered in the vascular system. As amended herein, claim 1 specifies that the outer tube of the sheath has a durometer of about 30 to 60 on the Shore D hardness scale.

Prior art small diameter sheaths, referred to in the present specification (paragraph [0023]) as sheaths having a diameter of about 5 to 12 French, generally include an outer layer or jacket primarily comprised of a material having a high durometer, e.g., between about 60 and 80 on the Shore D scale. Such high durometer materials provide favorable kink resistance to the sheath, and also provide sufficient strength to enable the small diameter sheath to be guided through small diameter passageways in the vasculature. Using this same high durometer material with a larger diameter sheath would still result in a sheath that is kink resistant, but one that is more difficult to bend in actual practice than are smaller size sheaths. In some applications, this lack of flexibility may preclude use of the large diameter sheath altogether, or at a minimum, add a

degree of difficulty and uncertainty to the procedure that would not be present if a more flexible sheath was used. Thus, such large diameter sheaths as claimed herein advantageously include a softer (e.g., lower durometer) outer jacket material when compared to the jacket material commonly used in small diameter sheaths. This softer outer jacket allows large diameter sheaths to bend more easily when inserted into the vasculature.

As the Examiner stated in the Office Action, Parker discloses numerous features of the invention claimed herein. Importantly, however, Parker does not specify the beneficial relationship between inner sheath diameter and outer tube durometer for large diameter sheaths as claimed in claim 1.

The secondary Lepulu reference was cited for teaching a tube having a passageway extending therethrough ranging from a diameter of 19-32 French, and having a side port in the sheath wall. Generally speaking, Lepulu is directed to a cannula for use in cardiopulmonary bypass. The cannula has alternating reinforced sections and nonreinforced sections, wherein the nonreinforced sections having openings communicating with the lumen of the cannula. The nonreinforced sections are plain tubing and the alternating reinforced sections are formed by helically winding a coated elongate member around a mandrel.

As with Parker, Lepulu also does not teach the beneficial relationship between inner sheath diameter and outer tube durometer as claimed in claim 1. More particularly, Lepulu does not teach or suggest such relationship with a sheath comprising the components recited in the present claims. Lepulu does not deal with durometer issues regarding an outer sheath layer as described above, and in fact, does not even recite a durometer range of the outer portion of the sheath. The skilled artisan would receive no guidance from Lepulu when dealing with the problem of passing a large diameter sheath through a tortuous pathway within, e.g., the vascular system of a patient.

Applicants herein have uniquely combined disparate features in a manner to provide a sheath that has a large diameter, and yet is capable of readily navigating tortuous pathways encountered in the vascular system. Neither of the

cited references, either individually or in combination, teaches a sheath that combines these beneficial features.

Based upon the foregoing, Applicant submits that the subject matter of claim 1 is not obvious in view of the cited prior art. The dependent claims to claim 1 are even further removed from the teachings of the cited references. For example, claims 4 and 5 teach inside diameters of the sheath that have a narrower range than specified in claim 1. Claims 14 and 15 teach narrower hardness ranges for the outer tube than recited in claim 1. Claim 20 (as well as new claim 29) deal with the radiopaque marker tube. According to claim 20, the marker tube is bonded to the outer tube by a thermal bond. According to claim 29, the radiographic marker tube and the outer tube are formed from the same polymer having the same durometer, and the tubes are bonded together by a thermal bond. By forming the marker tube and the outer tube from the same polymer having the same durometer, a more secure bond is formed therebetween. Applicants submit that the subject matter of these claims is also not taught in the citations.

Claims 7-9, 11, and 13.

Claims 7-9, 11, and 13 were rejected under 35 USC 103(a) as being unpatentable over Parker (US 5,700,253) in view of Lepulu et al (US 6,533,770), and further in view of Parker (US 5,769,830) ("Parker '830").

Claims 7-9, 11 and 13 depend, directly or indirectly, from independent claim 1, and therefore include all of its limitations. Therefore, these claims are not obvious in view of the cited references for at least the same reasons that claim 1 is not obvious.

In addition, Parker '830 is directed a guiding catheter having a soft tip for atraumatic insertion into coronary vessels. The guiding catheter includes a main tubular portion and a soft tubular tip with cooperating bonding surfaces for increasing the contact area and strength of the thermal bond therebetween. The main portion preferably includes an inner layer of lubricious material, an outer layer of a polyether block amide, and a reinforcing braid positioned

therebetween. The main tubular portion also includes distal and proximal segments heat shrink bonded together to provide changes in durometer along the length of the catheter.

The disclosure of Parker '830 describes the guiding catheter as having an outside diameter of about 8 French. See, e.g., Col. 2, line 48; Col. 4, line 25. A representative example of the diameter of the inner layer 25 is said to be 6.7 French. Col. 4, line 48. Another example states that the guiding catheter has an inside diameter of approximately 0.082" (6.2 French). Col. 4, line 27. The Examiner stated that Parker '830 teaches a tube having a Shore D hardness from 50-65. However the passage of Parker '830 cited by the Examiner (Col. 4, lines 40-50) states that this is the durometer of the inner layer 25, not the outer layer as claimed herein.

Thus, Applicants respectfully submit that a skilled artisan dealing with the problems associated with the flexibility of large diameter sheaths in tortuous pathways would not find the solution in Parker '830. Parker '830 is directed to other issues encountered with a guiding catheter, and does not purport to address the problems solved by the claimed invention.

#### Claims 16-19.

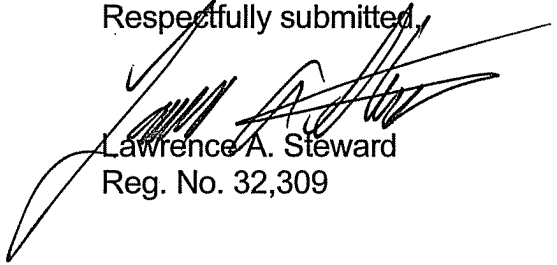
Claims 16-19 were rejected under 35 USC 103(a) as being unpatentable over Parker (US 5,700,253) in view of Lepulu et al (US 6,533,770).

Claims 16-19 add additional details to the claims regarding the width and spacings of the coil and the coil turns (claim 16). These claims depend, directly or indirectly, from claim 1, and therefore include all of its limitations. This, these claims are not obvious in view of the citations for at least the same reasons that claim 1 is not obvious.

**Conclusion:**

Based on the foregoing, Applicants submit that the rejections to the claims have been overcome, and that all claims 1, 2, 4-6, 8-21, and 29 are in condition for allowance. Accordingly, Applicants respectfully request the timely issuance of a Notice of Allowance. If the Examiner has any further questions, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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